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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,586	03/17/2004	Bettina Mockel	021123-0307839	2731
909	7590	01/11/2006	EXAMINER	
PILLSBURY WINTHROP SHAW PITTMAN, LLP			FRONDA, CHRISTIAN L	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	
			1652	
DATE MAILED: 01/11/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/801,586	MOCKEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 26-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/838,564.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/17/04</u> . | 6) <input type="checkbox"/> Other: ____.  |

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### **DETAILED ACTION**

1. Claims 26-45 are pending and under consideration.
2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No.09/838,564, filed on 04/20/2001.

#### ***Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 27, 28, 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 27, the phrase "other genes of the biosynthetic pathway" renders the claim vague and indefinite because the specific enzymes and pathways are not recited in the claim. Thus, the metes and bounds of the claim are not certain.

In claim 28, the phrase "metabolic pathways" renders the claim vague and indefinite because the specific "metabolic pathways" are not recited and it is not known what specific enzymes are involved to make any product.

In claim 35, the phrase succinyl-CoA synthetase enzymatic activity encoding sucC or sucD" renders the claim vague and indefinite because it is not certain how the recited enzymatic activity can actually encode a polynucleotide. It is known in the art that polynucleotide encode their respective polypeptides.

#### ***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and

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process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 26, 27, 34-40, 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the evaluation of the claims for compliance with the written description requirement of 35 U.S.C. 112, of particular relevance is 66 FR 1099, Friday, January 5, 2001, which states:

*“Eli Lilly* explains that a chemical compound’s name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because “it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Thus *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed.” (see p. 1100, 1<sup>st</sup> column, line 47 to 2<sup>nd</sup> column, line 2).

The claims are genus claims directed a process using a genus of sucC genes, variants, and mutants thereof and a genus of sucD genes, variants, and mutants thereof. The scope of each genus includes many members with widely differing structural, chemical, and physiochemical properties including widely differing nucleotide sequences. Furthermore, each genus is highly variable because a significant number of structural differences between genus members exists.

While the specification discloses an isolated polynucleotides of SEQ ID NOs: 1 or 4 encoding a polypeptide having succinyl-CoA synthetase activity consisting of the amino acid sequence of SEQ ID NOs: 2 or 3, the recitation of the names “sucC” and “sucD” do not define any structural features commonly possessed by each genus that distinguish them from others. Furthermore, the specification does not describe and define any structural features commonly possessed by each claimed genus. Thus, one skilled in the art cannot visualize or recognize the identity of the members of each genus.

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The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of the claimed genus of sucC genes, variants, and mutants thereof and a genus of sucD genes, variants, and mutants thereof.

The claims are additionally rejected for the following reasons. Gene elements which are not particularly described, including regulatory elements and untranslated regions, are essential to the function of the claimed invention since the claims as written encompass the sucC gene and sucD gene. Furthermore, claims 36 and 37 recite several genes encoding different proteins and enzymes. The art indicates that the structure of genes with regulatory elements and untranslated regions is empirically determined. Therefore, the structure of these elements which applicants considers as being essential to the function of the claim are not conventional in the art.

There is no known or disclosed correlation between the coding region of a polynucleotide encoding SEQ ID NO: 2 or SEQ ID NO: 4 and the structure of the non-described regulatory elements and untranslated regions of the sucC gene or sucD gene. In view of the above considerations, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of any sucC gene or sucD gene or any of the genes recited in claim 36 and 37.

7. Claims 26-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for producing L-glutamate by culturing a coryneform bacterium comprising an inactivated polynucleotide of SEQ ID NO: 1 or SEQ ID NO 4; does not reasonably provide enablement for a process for producing any of the recited amino acids by culturing any

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bacterial cell comprising any attenuated sucC and/or sucD gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass a process for producing any of the recited amino acids by culturing any bacterial cell comprising any attenuated sucC and/or sucD gene. The specification provides guidance and examples for the polynucleotide of SEQ ID NO: 1 and SEQ ID NO 4 from *Corynebacterium glutamicum* encoding succinyl-CoA synthetase; *C. glutamicum* DSM 13750 and DSM 13749 that is genetically engineered to have an inactivation of SEQ ID NO: 1 and SEQ ID NO: 4; and culturing of the genetically engineered *C. glutamicum* DSM 13750 and DSM 13749 which produces glutamate (see Tables 1 and 2 of the specification).

However, the specification does not provide guidance, prediction, and working examples for making a process for producing any of the recited amino acid by culturing any coryneform bacterium strain comprising any sucC or sucD gene of any nucleotide sequence and structure. Thus, an undue amount of trial and error experimentation must be preformed to search and screen for any sucC or sucD gene from any coryneform bacterium strain and determining whether attenuating the sucC or sucD gene will result in production of any of the recited L-amino acid including glutamate.

In view of the above considerations, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

8. Claim 41, 43, 44, 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described

in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the *E. coli* strain DSM 13750 and *E. coli* strain DSM 13749 are required to practice the claimed invention. As such they must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise known and readily available to the

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public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by an enabling deposit of the said strains.

The process disclosed in the specification to make the plasmid vectors does not appear to be repeatable. The nucleotide sequences of the plasmid vectors are not fully disclosed, nor have all the nucleotide sequences required for their construction been shown to be biblically known and freely available. The specification does not disclose a repeatable process to obtain the plasmid vectors and it is not apparent if the nucleotide sequences are readily available to the public. It is not apparent if the source materials to make the plasmids are both known and readily available to the public.

Applicants' referral to deposit numbers DSM 13750 and DSM 13749 is noted but is considered insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met since there is no indication in the specification as to public availability.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific microorganism has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809 and MPEP 2402-2411.05, the applicant may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his/her signature and registration number, showing that:

- (1) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (2) all restriction upon availability to the public will be irrevocably removed upon granting of the patent;
- (3) the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (4) the deposit will be replaced if it should ever become inviable.

### *Conclusion*

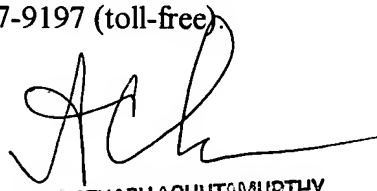
9. No claim is allowed.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



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